K111357

Traditional 510(k)
Section 5: 510(k) Summary

OCT - 3 2011

1. Applicant's Name and Address

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Senior Regulatory Affairs Specialist

2. Date of Submission: May 12, 2011

3. Name of the Device

Trade Name:	Straumann Narrow Neck CrossFit® (NNC) Ø3.3mm Dental Implant System
Common Name:	NNC Ø3.3mm Dental Implant
Classification Name:	Implant, Endosseous, Root-form
Regulation Number:	§872.3640

1. Legally Marketed Device to which Equivalence is Claimed (Predicate Device)

K083550, Straumann Dental Implant System
K060958, Straumann Narrow Neck Dental Implants
K072497, P.004 NC Gold Abutment for Crowns
K092814, Straumann NC Temporary Abutments
K071585, NC Closure Screws
K960634, Esthetic Healing Caps

5. Description of the Device

The proposed Straumann Narrow Neck Connection CrossFit® (NNC) Ø3.3mm Dental Implant System is a new product to be added to our current Tissue Level implant product portfolio. Straumann currently has a Tissue Level dental implant with a Ø3.5mm prosthetic platform with an external hexagon abutment; the abutment and implant are machined as one piece.

The proposed system introduces a Ø3.5mm prosthetic platform with an internal CrossFit connection. The proposed system is an implant with no attached abutment. The abutment is sold separately.

The purpose of this 510(k) Premarket Notification is to introduce:

a. Narrow Neck CrossFit® (NNC) Ø3.3mm dental implant in 4 lengths; 8.0mm, 10.0mm, 12.0mm and 14.0m,
b. Gold abutment for use with the crown,
c. NNC posts for temporary restorations made from Titanium. The posts are to be used for a single crown restoration or bridge,
d. NNC closure screws (0mm and 1.5mm),
e. Healing caps (3.0mm, 4.5mm and 2.0mm),
f. NNC impression post, open tray, and
g. NNC analog.

6. Intended Use of the Device

Narrow Neck CrossFit® (NNC) Dental Implants

Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only

large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Specific indications for small diameter (Ø 3.3 mm) implants:
Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in the molar region is not recommended.

Straumann Narrow Neck CrossFit® (NNC) Gold Abutment for Crowns
Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.

Straumann Narrow Neck CrossFit® (NNC) Temporary Abutments

The Straumann NNC Temporary Abutments are indicated for use in Straumann NNC Tissue Level Implants for temporary restorations of single crowns and bridges for up to six months.

Straumann Narrow Neck CrossFit® (NNC) Healing Caps and Closure Screws

Straumann NNC Healing Caps and NNC Closure Screws are intended for use with the Straumann NNC Tissue Level Implant System to protect the inner configuration of the implant. Healing Caps have a secondary function to maintain, stabilize and form the soft tissue during the healing process.

7. Technological Characteristics

The body of the proposed implant has a threaded Ø3.3mm implant body design with the SLActive surface of Straumann's TiZr Implant currently

cleared under K083550. The material of the proposed implant is Straumann's Titanium Zirconium (TiZr) currently cleared under K083550. This design proposes a narrow Tissue Level implant with an internal connection for smaller interdental spaces. There are no changes to the materials, indications for use, fundamental operating principles, or sterilization processes or procedures as a result of the new implant and its accessories and components. No new surgical instruments are being introduced as placement of the proposed implant will follow the established surgical protocols of the currently cleared Straumann Dental Implant Systems. The proposed devices are substantially equivalent to the currently marketed devices. .

8. Performance Testing

Verification and validation testing were performed to ensure that the devices subject to this 510(k) Premarket Notification function as intended and that design input matches design output. Testing included:

1. Performance Testing
    a. Fatigue Testing in accordance to FDA guidance document "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments."

9. Conclusion

The results from the testing conducted demonstrated that the Straumann Narrow Neck CrossFit® (NNC) Ø3.3mm Dental Implant System functions as intended and met the pre-determined acceptance criteria.

The Straumann Narrow Neck CrossFit® (NNC) Ø3.3mm Dental Implant System is a validated system. The results of the performance bench testing and risk analysis indicate that the Straumann Narrow Neck

CrossFit (NNC) Ø3.3mm Dental Implant System is substantially equivalent to the named predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Elaine Alan
Senior Regulatory Affairs Specialist
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

OCT - 3 2011

Re: K111357
Trade/Device Name: Straumann Narrow Neck CrossFit (NNC) 03.3 Dental Implant System, Straumann Narrow Neck CrossFit (NNC) Gold Abutment for Crowns, Straumann Narrow Neck CrossFit (NNC) Temporary Abutments, Straumann Narrow Neck CrossFit (NNC) Healing Caps and Closure Screws
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 19, 2011
Received: August 22, 2011

Dear Ms. Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111357

Device Name: Narrow Neck CrossFit (NNC) Ø3.3mm Dental Implant System

Indications for Use:

Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Specific indications for small diameter (Ø 3.3 mm) implants:
Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in the molar region is not recommended.

Prescription Use___X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of DCRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111357

Indications for Use

510(k) Number (if known):

Device Name: Straumann Narrow Neck CrossFit (NNC) Gold Abutment for Crowns

Indications for Use:

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.

Prescription Use__X__ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111357

Indications for Use

510(k) Number (if known):

Device Name: Straumann Narrow Neck CrossFit (NNC) Temporary Abutments

Indications for Use:

The Straumann NNC Temporary Abutments are indicated for use in Straumann NNC Tissue Level Implants for temporary restorations of single crowns and bridges for up to six months.

Prescription Use__X__ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k111357

Indications for Use

510(k) Number (if known):

Device Name: Straumann Narrow Neck CrossFit (NNC) Healing Caps and Closure Screws

Indications for Use:

Straumann NNC Healing Caps and NNC Closure Screws are intended for use with the Straumann NNC Tissue Level Implant system to protect the inner configuration of the implant. Healing Caps have a secondary function to maintain, stabilize and form the soft tissue during the healing process.

Prescription Use___X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of DCRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k 111357